

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical Trial Phase IIa, on Amelioration of Decompensated Liver Cirrhosis with Mesenchymal Stem Cells-derived Exosomes

Protocol summary

Registration timing: **prospective**

Study aim

Clinical trial Phase IIa, on amelioration of decompensated Liver Cirrhosis with Mesenchymal Stem Cells derived exosome

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

Registration date

2023-03-11, 1401/12/20

Design

A phase IIa clinical trial on decompensated liver cirrhosis patients with 15 individuals

Registrant information

Name

Kaveh Baghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

Upon recruitment clinical information will be obtained via an interview and use of a structured questionnaire. Liver function will be evaluated at baseline, 2 months and 4 months after administration. Patients will be reviewed by a physician at 2 months and 4 months for development of any potential adverse events including hypersensitivity or allergy to MSc derived exosome.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Eligible patients were at least 18-year-old with a clinical and/or pathologic diagnosis of liver decompensated Cirrhosis; Ages Eligible for Study: 18 Years to 75 Years (Adult, Older Adult) ; Sexes Eligible for Study: All (male and female); Able to understand and willing to voluntarily sign an informed consent form (ICF); Child score class B or C.

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

15 enrolled patients will receive standard medication plus Msc derived exosome at a final dose of 40mg, one time per week for three weeks.

Main outcome variables

Liver function including CHILD score and MELD score will be evaluated at baseline, 8 weeks and 16 weeks after administration.

Scientific title

Clinical Trial Phase IIa, on Amelioration of Decompensated Liver Cirrhosis with Mesenchymal Stem Cells-derived Exosomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048342N3**

Registration date: **2023-03-11, 1401/12/20**

Public title

Effect of Mesenchymal Stem Cells-derived Exosomes in Decompensated Liver Cirrhosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Able to understand and willing to voluntarily sign an informed consent form (ICF) authorization. Males or females between 18-75 years old with a clinically confirmed diagnosis of Liver cirrhosis with any etiology, except viral cirrhosis. Child score class B or C.

Exclusion criteria:

Known cardiovascular disease. a) History of hepatocellular carcinoma (HCC). b) History of malignancy within the past 5 years or ongoing malignancy other than basal cell carcinoma, or resected noninvasive cutaneous squamous carcinoma at the time of Screening visit. c) Active, serious infections that require parenteral antibiotic or antifungal therapy within 30 days prior to Screening visit. Females who are pregnant or breastfeeding. Current or anticipated treatment with radiation therapy, cytotoxic chemotherapeutic agents and immunomodulating agents (such as systemic corticosteroids, interleukins, interferons). Use of any experimental medications within the last 6 months of Screening Visit. Any other clinically significant disorders or prior therapy that, in the opinion of the investigator, would make the subject unsuitable for the study or unable to comply with the dosing and protocol requirements. Weight loss of >5% within 6 months prior to Screening, based on subject's reporting. Currently or participated in a weight loss program within the last 6 months. Any history of bariatric surgery. Diabetes mellitus Type I. Daily alcohol intake >20 ml (2 units)/day for women and 30 ml (3 units)/day for men (on average), as per Alcohol Use Disorders Identification Test (AUDIT) questionnaire at Screening and plan to consume the same alcohol amount referenced above during the trial. Use of any immunosuppressive medication, anti-inflammatory monoclonal antibody treatment, or chronic systemic corticosteroids >10 mg prednisone-equivalent concurrently or within 1 year prior to Screening. Uncontrolled or clinically unstable thyroid disease, in the judgment of the Principal Investigator. Uncontrolled arterial hypertension Any severe, acute, or chronic medical or psychiatric condition that may increase the risk associated with study participation or study drug administration, may interfere with the informed consent process and/or with compliance with the requirements of the study, or may interfere with the interpretation of study results and, in the investigator's opinion, would make the subject inappropriate for entry into this study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Science

Street address

Research Institute for Gastroenterology and Liver Diseases, taleghani hospital, Arabi st., Velenjak ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985714711

Approval date

2022-11-28, 1401/09/07

Ethics committee reference number

IR.SBMU.RIGLD.REC.1401.016

Health conditions studied

1

Description of health condition studied

Decompensated Liver Cirrhosis

ICD-10 code

K74

ICD-10 code description

Fibrosis and cirrhosis of liver

Primary outcomes

1

Description

Liver function by MELD score

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Calculation of MELD score based on patient's laboratory values for serum creatinine, bilirubin, international normalized ratio for prothrombin time, and sodium.

2

Description

Liver function by CHILD score

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Calculation of CHILD score based on patient's laboratory values for serum bilirubin, albumin, international normalized ratio for prothrombin time, ascites, and encephalopathy.

Secondary outcomes

1

Description

Change in liver enzyme AST

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Blood test

2

Description

Change in liver enzyme ALT

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Blood test

3

Description

international normalized ratio (INR) for prothrombin time

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Blood test

4

Description

Bilirubin

Timepoint

Baseline, after 2 and 4 months of the trial

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: patients will receive standard medication plus MSC-derived exosomes at a final dose of 40mg in three weeks. Standard medication includes: a) treatment of the underlying cause of cirrhosis such as drug treatment of hepatitis B and C. b) symptomatic treatment of port complications such as ascites, prevention of variceal bleeding, treatment and prevention of hepatic encephalopathy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Liver Diseases clinic

Full name of responsible person

Behzad Hatami

Street address

Gastroenterology and Liver Diseases clinic, Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Zali

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nnzali@hotmail.com

Grant name

Research Institute for Gastroenterology and Liver Diseases

Grant code / Reference number

1208

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

30
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
30
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

3

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
40
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behzad Hatami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterologist
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Person responsible for scientific inquiries

Contact
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Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Medical Biology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of data which is related to main outcome could be share.

When the data will become available and for how long

starting in 2024

To whom data/document is available

It would be available for people working in academic institutions and those are in businesses can also apply to receive it.

Under which criteria data/document could be used

It is depends on requests.

From where data/document is obtainable

Corresponding: Dr. Behzad Hatami
"bhz_hatami@yahoo.com" Dr. Kaveh Baghaei
"kavehbaghai@gmail.com"

What processes are involved for a request to access data/document

-Request - Early consideration in 1 week - Conversations
- Provide possible request between 2-4 weeks

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Taha Aghajanzadeh

Position

Researcher

Latest degree

Master

Other areas of specialty/work

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